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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/297,899 05/10/99 MARNFELDT G 06275/184001

QM12/1108

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EXAMINER

WEISS JR, J

ART UNIT	PAPER NUMBER
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3761

DATE MAILED:

11/08/00

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/297,899

Applicant(s)
Marnfeldt et al.

Examiner
Joseph Weiss

Group Art Unit
3761



☒ Responsive to communication(s) filed on May 10, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-15 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-15 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In lines 9 & 15, the claims are rendered indefinite by use of the language "one of opened or closed" and "one of open or close the same." It appears applicant is setting forth an electrical switch having a first open position and a second closed position corresponding to the delivery of a dose to the inhalation channel to trigger the counting mechanism/display, however, this is not clearly born by the noted current language, resulting in speculation, thus rendering the claims indefinite.

3. Claim 1 recites the limitation "the usage" in ⁱⁿ7 of the claim. There is insufficient antecedent basis for this limitation in the claim.
4. Claims 11 & 12 recites the limitation "the number of doses" in line 2 of each respective claim. There is insufficient antecedent basis for this limitation in the claim.
5. Claim 9 recites the limitation "the outer surface" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ambrosio et al (5687710) in view of Wolf et al (5505195).

Ambrosio discloses an inhaler for delivering medicament (see fig 1-4), with an inhalation channel (64), a rotatable dosing unit (22), a dosing element (182), a dose counting unit (580), a rotatable member (90) connected to the dosing unit, which is a cam (a rotating or sliding piece in a mechanical linkage) having a camming surface (Fig 9), configured to rotate the dosing unit to provide a dose of medicament to the inhalation channel, but Ambrosio does not disclose the detailed electronic counting mechanism as set forth by applicant. However, Wolf discloses such. To include an electronic display (1035), with an electric circuit (401, 402 & 403), the circuit including/being/having a switch (435 or 436) comprising a contact element (435 or 436) which have a first "open" position and a second closed "position" to break or complete the circuit which corresponds to the dosing mechanism's actuation and its return to the prior state indicative of delivery of a dose to the inhalation channel. The references are analogous since they are from the same field of endeavor, the inhaler arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Wolf

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and used them with the device of Ambrosio. The suggestion/motivation for doing so would have been to since Wolf discloses a electronic device for counting doses on an inhaler, notably at the base in fig 10, and since Ambrosio discloses the use of an electronic dose counting means with its inhaler (col. 25, lines 23-28). Therefore it would have been obvious to combine the references to obtain the instant application's invention.

In regards to claim 2, The device suggested by Ambrosio & wolf discloses the use of two switches (435 & 436) which are contact elements and a rotatable member (90) which has a first & second camming surface (Fig 9 & 10) to function as cams to make or break contact with the contact elements.

In regards to claims 3 & 4, the reference noted above substantially disclose the claimed invention except for the use of a plurality of dosing elements/cams & cam surfaces, i.e. the duplication of a known part for a known purpose.

It is noted that applicant's specification does not set forth this duplication of a known part for a known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of this duplication of a known part for a known purpose to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Also In regards to claims 3 & 4, the reference noted above substantially disclose the claimed invention except for the maintenance of a constant angular spacing.

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It is noted that applicant's specification does not set forth this constant angular spacing, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of a constant angular spacing of the cams/cam surfaces to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 5, Wolf discloses the switches 435 & 436 as being rotationally offset (see figs 4a & 4b).

In regards to claims 7 & 8, the reference noted above substantially disclose the claimed invention except for the use of a resilient biasing arm with a first portion for riding on the cam surface and a second portion for providing a contact means to facilitate lateral movement.

It is noted that applicant's specification does not set forth this arrangement/feature, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of this arrangement/feature to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather

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that to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 9, the reference noted above substantially disclose the claimed invention except for the use of a bend in the contact arm.

It is noted that applicant's specification does not set forth this feature, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of a bent contact arm to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 10, Ambrosio substantially discloses the instant application's invention to include the use of a shaft (188) with a surface (190) providing an external/internal spline & another element (218) with surface (222) providing another external/internal spline so that when engaged they facilitate the dosing unit and the rotatable member to be rotated co-commitment, however these elements are not directly part of the dosing unit & rotatable member, as set forth by applicant, i.e. a reversal or rearrangement of known parts for a known purpose.

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It is noted that applicant's specification does not set forth this reversal or rearrangement of known parts for a known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of this reversal or rearrangement of known parts for a known purpose to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claims 11-13, Wolf discloses the display as displaying doses used, doses remaining and is fully capable of being programmed to alternatively display dosage information (col. 13 lines 46-67).

In regards to claim 14, Wolf discloses the display as being an LCD display (1035, col. 13 line 52).

In regards to claim 15, The device suggested by Ambrosio & wolf discloses a grip so the user may grip the device and rotate it to actuate the dosing mechanism (110 of Wolf & 320 of Ambrosio).

Allowable Subject Matter

8. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 6029659, 5829434, 5740792, 5363842, 5020527

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM.

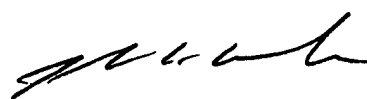
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, John G. Weiss, can be reached at telephone number (703) 308-2702. The official fax number for this group is (703) 305-3590 or x3591.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.



J. Weiss

October 31, 2000



John G. Weiss
Supervisory Patent Examiner
Group 3700

ATTACHMENT TO AND MODIFICATION OF
NOTICE OF ALLOWABILITY (PTO-37)
(November, 2000)

NO EXTENSIONS OF TIME ARE PERMITTED TO FILE CORRECTED OR FORMAL DRAWINGS, OR A SUBSTITUTE OATH OR DECLARATION, notwithstanding any indication to the contrary in the attached Notice of Allowability (PTO-37).

If the following language appears on the attached Notice of Allowability, the portion lined through below is of no force and effect and is to be ignored¹:

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS** FROM THE "DATE MAILED" of this Office action. Failure to comply will result in ABANDONMENT of this application. ~~Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).~~

Similar language appearing in any attachments to the Notice of Allowability, such as in an Examiner's Amendment/Comment or in a Notice of Draftperson's Patent Drawing Review, PTO-948, is also to be ignored.

¹ The language which is crossed out is contrary to amended 37 CFR 1.85(c) and 1.136. See "Changes to Implement the Patent Business Goals", 65 Fed. Reg. 54603, 54629, 54641, 54670, 54674 (September 8, 2000), 1238 Off. Gaz. Pat. Office 77, 99, 110, 135, 139 (September 19, 2000).